K133054

MAY 1 2 2014

510(k) Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: ___02/26/2014___

1. Submission Applicant / Submitter:

MARUCHI
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220-962, Republic of Korea

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2. Submission Correspondent:

Priscilla Chung
LK Consulting Group USA, Inc.
2651 E Chapman Ave Ste 110,
Fullerton CA 92833
Phone: 714-202-5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device:

Proprietary Name:	ENDOSEAL
Common Name:	Root Filling Material
Classification Name:	Root Canal Filling Resin
Classification:	Class II, 21 CFR 872.3820
Classification Product Code:	KIF

4. Predicate Device:

ENDOCEM MTA (Mineral Trioxide Aggregate) (K112078) by MARUCHI

5. Device Description:

The raw materials of the ENDOSEAL are Natural Pure Cement, Zirconium dioxide, and Citric acid anhydrous, and the device has been showing good sealing ability and biocompatibility. It is prepared as a mixture of powder and water, and it is used in a putty form which gradually hardens in the oral environment.

6. Intended Use:

- Repair of perforation
- Root canal filling

7. Performance Data(Non-Clinical):

The following properties were tested based on the referenced standard. All the test results met the preset test criteria.

- ISO 6876 – Visual, Packaging, Setting time, Solubility and Radiopacity
- ISO 7405 - Cytotoxicity
- ISO 10993-10 - Skin sensitization, Local Lymph Node Assay, LLNA
- ISO 10993-11 - Acute systemic toxicity
- Other bench testing - Capacity and pH (Saline Extracts)

8. Substantial Equivalence

ENDOSEAL has similar physical and biocompatible properties, and demonstrates comparable performance specifications to ENDOCEM MTA (Mineral Trioxide Aggregate). In addition, ENDOSEAL has a comparable delivery system to ENDOCEM MTA.
In comparison, ENDOSEAL contains Zirconium dioxide and Citric acid anhydrous, but Bismuth Trioxide, which is in ENDOCEM MTA, is not present in ENDOSEAL.
The results of bench and biocompatibility testing performed demonstrate that this difference does not raise any new questions as to safety and effectiveness.
Therefore, it is concluded that ENDOSEAL is substantially equivalent in safety and effectiveness to the predicate device.

9. Conclusion:

Based on the testing results, MARUCHI concludes that the ENDOSEAL is substantially equivalent in safety and effectiveness to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 12, 2014

MARUCHI
C/O Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Incorporated
2651 East Chapman Avenue, Suite 110
Fullerton, CA 92833

Re: K133054
Trade/Device Name: ENDOSEAL
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Code: KIF
Dated: February 26, 2014
Received: March 4, 2014

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133054

Device Name
ENDOSEAL

Indications for Use *(Describe)*

- Repair of perforation
- Root canal filling

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sheena A. Green -S
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